

7-SM-13

THE COLORADO STATE BOARD OF PHARMACY
Special Report

Date: 20 July 2012

Inspector: Susan S. Martin

Subject: New England Compounding Pharmacy, Inc. (WHO 7832)

Background:

On 7/17/12, I visited Delta County Memorial Hospital, 1501 E. 3rd St. Delta, CO 81416 to conduct a routine inspection. While reviewing the records of receipt for prescription drugs, I located an invoice from New England Compounding Center, Inc., PO Box 4146, Woburn, MA 01888-416 detailing receipt of a quantity of 46 hyaluronidase 150U/ml, 1 ml injection (a compounded prescription drug) on 6/28/12 (Attachment 1). I asked the pharmacist manager, Mark Carlton (RPH 11282), if they had any of this product in the pharmacy. He showed me a container of vials of this product and I took several pictures of one (Attachment 2). Upon return to the office, I searched the CAVU E-License database (the licensing database for the Colorado Department of Regulatory Agencies) for information concerning New England Compounding Center Inc.'s registration status. The name "New England Compounding Center, Inc." is not found in the E-License database, however, the following entities were located (Attachment 3):

- 1) New England Compounding Center is the DBA (doing business as) and owner of New England Compounding Pharmacy, Inc., an out-of-state wholesaler located at 697 Waverly St., Framingham, MA 01702 (WHO 7832).
- 2) New England Compounding Center is an out-of-state pharmacy, located at 697 Waverly St., Framingham, MA 01702 (OSP 5402).

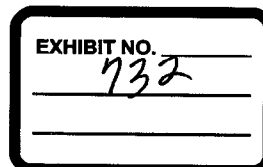
Neither of these registered entities is located at the address on the invoice from New England Compounding Center, Inc.

On 7/16/12, I spoke with Regina Barrell from the Food and Drug Administration to inquire whether New England Compounding Center, Inc. was registered as a manufacturer. She confirmed that they were not (Attachment 4).

During a routine inspection in 2011, Inspector Lisa Cornett located documentation of unregistered/unlicensed distribution of prescription drugs into Colorado by New England Compounding Center, Inc. (Attachment 5). As a result of her investigation, Case 2011-3973 was initiated and a Cease and Desist Order was issued to New England Compounding Center, Inc. on 4/15/11 (Attachment 6).

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BORP0006571

Martin, Susan

From: Barrell, Regina A <Regina.Barrell@fda.hhs.gov>
Sent: Monday, July 16, 2012 2:54 PM
To: Martin, Susan
Cc: Wardwell, Amber; Ota, Bruce R; Archdeacon, Karen N
Subject: FW: New England Compounding Center (NECC)
Attachments: Attachment - 1.pdf; Attachment - 2.pdf; Attachment - 3.pdf; hppscan45.pdf

Hi Sue:

I checked our Registration database and New England Compounding Center is not listed as having registered with us as a manufacturer. With this e-mail, I am copying our New England District Compliance staff with the information you provided (invoice for the injectable hyaluronidase to Delta County Memorial Hospital) along with the Cease and Desist documents Chris Gassen sent last year regarding NECC (see e-mail string below). I would suggest you get in touch with the Massachusetts Board of Pharmacy if you haven't already to inform them of the firm's activity and to see if there are any actions they may wish to take especially in light of your Cease and Desist Order.

I also checked the status of Wedgewood Pharmacy in New Jersey. They also are not listed in our database as having registered as a manufacturer. Under a separate e-mail, I will copy our New Jersey District Office with the invoice you collected, but as in the NECC case, you may wish to contact your counterparts with the New Jersey Board of Pharmacy.

Let me know if you have any questions or wish to discuss further.

Regina

From: Wardwell, Amber
Sent: Tuesday, May 10, 2011 3:07 PM
To: Barrell, Regina A; Archdeacon, Karen N; Ota, Bruce R
Subject: FW: New England Compounding Center (NECC)

Thanks Regina,

Bruce Ota is the CO for NECC. I'll ask him to follow up if we have any questions.

Amber

From: Barrell, Regina A
Sent: Tuesday, May 10, 2011 4:19 PM
To: Wardwell, Amber; Archdeacon, Karen N
Subject: FW: New England Compounding Center (NECC)

Hi Amber and Karen:

I had a phone call with Chris Gassen of the Colorado Board of Pharmacy regarding New England Compounding Center (NECC). Attached is the background information from Chris as well as the Cease and Desist Order that the Board issued to NECC regarding their illegal distribution of compounded drugs to hospitals in the Denver metropolitan area. The firm is neither registered or listed with the State to do business as a drug outlet. I know that you have some previous reg history with this firm and that they were the recipient of at least one warning letter. This is just FYI but if you have any questions, please feel to give me a call to discuss.

Regina

From: Gassen, Chris [<mailto:Chris.Gassen@dora.state.co.us>]
Sent: Tuesday, May 10, 2011 12:29 PM
To: Barrell, Regina A
Subject: New England Compounding Center (NECC)

Hi Regina,

Attachment – 1 is the report and exhibits that lead to the Cease and Desist Order;

Attachment – 2 is additional documents Pharmacy Board staff obtained at another facility (while related to NECC, it's unrelated to what actually led to the Cease and Desist Order); and

Attachment – 3 is the actual Cease and Desist Order.

As always, thanks for your help.

Chris

Chris Gassen
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2-LC-11

THE COLORADO STATE BOARD OF PHARMACY
Special Report

Date: 13 April 2011

Inspector: Lisa A. Cornett

Subject: New England Compounding Center, Inc., OSP 5402

Issue: Unregistered/Unlicensed Distribution of Prescription Drugs into Colorado

Details:

On 04/5/11, I conducted a routine inspection of Sky Ridge Medical Center, (PDO 168-01), 10101 Ridgeway Pkwy, Lone Tree, CO 80124. During the inspection, I collected records detailing the receipt of prescription drugs purchased from New England Compounding Center, Inc., PO Box 4146, Woburn, MA, 01888, a non-resident prescription drug outlet. This is a violation of CRS 12-22-130(2) and CRS 12-22-802(1).

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BORP0006584

BEFORE THE STATE BOARD OF PHARMACY

STATE OF COLORADO

Case No. 2011-3973

CEASE AND DESIST ORDER

IN THE MATTER OF THE UNAUTHORIZED AND UNLAWFUL DISTRIBUTION OF
PRESCRIPTION DRUGS AND/OR COMPOUNDED PRESCRIPTION DRUGS IN
COLORADO BY NEW ENGLAND COMPOUNDING CENTER, INC.,

Respondent.

Pursuant to guidance established by the Colorado State Board of Pharmacy ("Board") at its January 15, 2009 meeting, documentation has been considered, including, but not limited to, the written complaint dated April 13, 2011, 2011, in the above-captioned matter.

Based upon this review, the Board hereby finds that it has jurisdiction over Respondent and the subject matter herein, and that there exists credible evidence that Respondent has acted without the required license or registration, in violation of §12-22-130(2) and 12-22-802, C.R.S.

The Board finds as follows:

1. Respondent's location at 697 Waverly St, Framington, MA 01702 is licensed or registered with the Board as a nonresident prescription drug outlet to dispense and deliver prescription drugs and/or compounded prescription drugs in the State of Colorado pursuant only to valid, patient-specific prescription orders.
2. Respondent's location at 697 Waverly St, Framington, MA 01702 is not licensed or registered to distribute stock prescription drugs and/or compounded prescription drugs in the State of Colorado.
3. On or around January 17, 2011 and March 24, 2011, Respondent distributed a stock compounded prescription drug from 697 Waverly St, Framington, MA 01702 to a prescription drug outlet in the State of Colorado.
4. Respondent's conduct constitutes the unlawful distribution of prescription drugs into the State of Colorado, in violation of §12-22-130(2) and 12-22-802, C.R.S.

WHEREFORE, pursuant to §12-22-125.2(9), C.R.S., the Board hereby ORDERS that Respondent immediately CEASE AND DESIST in engaging in the unlawful distribution of prescription drugs in the State of Colorado, in violation of §§12-22-130(2) and 12-22-802, C.R.S.

Within ten days after service of this order to cease and desist, Respondent may request a hearing on whether such acts or practices in violation Article 22 of Title 12, C.R.S. have occurred. Such hearing shall be conducted pursuant to §§24-4-104 and 24-4-105, C.R.S.

The Board authorized the undersigned representative to sign this Cease and Desist Order on its behalf.

DATED this 15th day of April 2011.

STATE BOARD OF PHARMACY

BY: Wendy Anderson
Wendy Anderson
Program Director
1560 Broadway, Suite 1300
Denver, Colorado 80202

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CERTIFICATE OF SERVICE

This is to certify that I have duly served the within CEASE AND DESIST ORDER upon all parties herein by depositing copies of same in the United States mail, first-class postage prepaid, at Denver, Colorado, this 15th day of April 2011, addressed as follows:

New England Compounding Center, Inc.
Attn: Designated Representative
697 Waverly St
Framington, MA 01702



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